

REMARKS

Previous Restriction Requirement

Claims 1-17 and 33-48 are withdrawn from consideration as non-elected claims from a prior restriction requirement. Applicant has cancelled these claims from the application without prejudice. Applicant reserves the right to pursue these claims in one or several divisional and/or continuing applications.

Objections to Claims

The Examiner has objected to claims 30 and 31 due to various informalities.

Applicant has cancelled claims 27-32 without prejudice. Applicant reserves the right to pursue the subject matter of these claims in one or several continuing applications.

Rejection under 35 U.S.C. § 102

Claims 18-32 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,053,031 (hereinafter referred to as “Borsanyi”).

As previously noted, claims 27-32 are cancelled without prejudice. The rejection of these claims is now moot and is not addressed herein.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicant respectfully submits that the applied reference does not satisfy these criteria.

Claim 18 recites:

manually applying pressure to a working fluid contained in an actuator associated with an implantable pharmaceutical fluid delivery device, wherein the implantable pharmaceutical fluid delivery device comprises a first fluid reservoir and a second fluid reservoir, thereby causing a flow of the working fluid into the first fluid reservoir;

delivering to the treatment area a first dosage of pharmaceutical fluid from the second fluid reservoir, wherein the working fluid and the pharmaceutical fluid are different fluids; and

delivering to a treatment area a basal flow dosage of the pharmaceutical fluid from a constant flow pump as the first dosage is delivered, the constant flow pump associated with the implantable pharmaceutical fluid delivery device.

Borsanyi is directed to an implantable infusion system in which the discharge of the therapeutic agent is controlled by the patient. Specifically, the patient depresses an actuator or plunger to transfer the therapeutic agent from a holding reservoir to a dispensing reservoir. The holding reservoir is implemented utilizing elastomeric material. The elastomeric material tends to drive the therapeutic agent from the dispensing reservoir. A capillary element is disposed between the dispensing reservoir and the outlet port of the infusion system to restrict the flow of the therapeutic agent from the dispensing reservoir. Accordingly, the therapeutic agent is dispensed to the patient in a controlled manner over a period of time. *See* col. 2, lines 55-68 of Borsanyi.

Borsanyi differs from the claimed subject matter in many respects. Importantly, there is only one mode of dispensing the therapeutic agent in Borsanyi, i.e., the dispensing of the therapeutic agent from the dispensing reservoir. The subject matter of claim 18 involves two different modes of dispensing a therapeutic agent (which occur simultaneously). As recited in claim 18, a “first dosage of pharmaceutical fluid” is delivered from the second fluid reservoir. The delivery of first dosage occurs due to the working fluid of the actuator which was previously delivered to another reservoir due to manual application of pressure to the actuator. In addition to the first dosage, a basal flow dosage is delivered as a result of “a constant flow pump.” Borsanyi does not disclose such multiple modes of delivery of a pharmaceutical fluid and, as a result, the patient cannot obtain a temporarily higher rate of delivery of a pharmaceutical fluid in Borsanyi.

Accordingly, claim 18 is not anticipated by Borsanyi. Claims 19-26 depend from claim 18 and are likewise not anticipated by Borsanyi.

New Claims

Applicant has added new independent claim 49 and dependent claims 50-54. Claims 49-54 are supported by the original application. No new matter has been entered.

Claim 49 recites:

storing infusate in a main reservoir of the implantable infusion drug pump, wherein a substantially constant fluid pressure is provided to the infusate in the main reservoir;

driving infusate from the main reservoir through a flow restrictor and out through a discharge port of the implantable infusion drug pump at a substantially constant basal infusion rate;

providing a temporary bolus infusion rate in response to patient manipulation of an actuator of the implantable infusion drug pump, wherein the bolus infusion rate is provided simultaneously to the basal infusion rate, wherein the providing a temporary bolus infusion rate comprises: (i) drawing infusate from the main reservoir into a secondary reservoir using the actuator; and (ii) controlling a discharge rate from the secondary reservoir to the discharge port using a flow restrictor;

wherein the implantable infusion drug pump does not comprise an electrical motor or an electrical power supply.

For the reasons discussed above in regard to claim 18, Applicant respectfully submits that Borsanyi does not teach or suggest operating an implantable infusion drug pump that provides "a substantially constant basal infusion rate" and (simultaneously) "a temporary bolus infusion rate" in the manner recited by claim 49.

Claim 49 is patentable over Borsanyi. Claims 50-54 depend from claim 49 and are likewise patentable.

Conclusion

Applicant respectfully submits that the application is in condition for allowance and requests the Examiner to pass the application to issue. Applicant believes no fee is due with this response. However, if a fee is due, please charge Deposit Account No. 50-3906 from which the undersigned is authorized to draw.

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Respectfully submitted,

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